**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

# Form 8-K

**Current Report**
**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): March 13, 2019**

# FENNEC PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

| | |
|---|---|
| **001-32295** | |
| (Commission File Number) | |
| **British Columbia, Canada** | **20-0442384** |
| (State or other jurisdiction of incorporation) | (I.R.S. Employer Identification No.) |
| **PO Box 13628, 68 TW Alexander Drive, Research Triangle Park, NC** | **27709** |
| (Address of principal executive offices) | (Zip Code) |

**Registrant's telephone number, including area code: (919) 636-4530**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 2.02. Results of Operations and Financial Condition.**

On March 13, 2019, Fennec Pharmaceuticals Inc. issued a news release announcing the fourth-quarter and full-year financial results for the period ended December 31, 2018. A copy of the news release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including the exhibit attached hereto, is being furnished and shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, unless such subsequent filing specifically references this Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
| --- | --- |
| Exhibit 99.1 | Press Release dated March 13, 2019 |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

FENNEC PHARMACEUTICALS INC.

Date March 13, 2019

By: /s/ Robert Andrade
Robert Andrade
Chief Financial Officer

**Exhibit 99.1**

**FENNEC PROVIDES BUSINESS UPDATE AND ANNOUNCES FISCAL YEAR 2018 FINANCIAL RESULTS**

- **Initiated rolling New Drug Application to U.S. FDA for PEDMARK™**
- **Secured $12. 5 million debt financing to support a potential commercial launch**
- **Strong financial position with $22.8 million in cash and no debt**
- **Targeted commercial launch in 2020**

***Research Triangle Park, NC, March 13, 2019 –*** Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a specialty pharmaceutical company focused on the development of PEDMARK™ (a unique formulation of sodium thiosulfate (STS)) for the prevention of platinum-induced ototoxicity in pediatric patients, today reported financial results for the fiscal year ended December 31, 2018.

"Throughout 2018 we were pleased to continue making progress on the advance of PEDMARK™ towards regulatory approval in the U.S. and EU," said Rosty Raykov, chief executive officer of Fennec. "Major accomplishments over the year included approval of our Pediatric Investigation Plan, confirmation of Pediatric Use Marketing Authorization eligibility in the EU and the initiation of our NDA in the U.S. This year, we remain focused on finalizing submissions in both the U.S. and EU and preparations for the potential launch of PEDMARK™ in 2020. "

**Recent Corporate Highlights and Upcoming Milestones**

- In December 2018, following a pre-submission meeting with the FDA, Fennec initiated a rolling New Drug Application (NDA) for PEDMARK™ in patients 1 month to <18 years of age with localized, non-metastatic, solid tumors. The NDA submission process is currently well underway. The Company has notified the FDA that the drug substance manufacturer for PEDMARK™ was recently acquired requiring a site transition for the commercial manufacturing site. The new facility of the acquiring company has large scale commercial capabilities and a proven and extensive track record of successful FDA inspections and product launches. As such, full submission is targeted for late 2019 to early 2020. If approved, Fennec expects a first commercial launch for PEDMARK™ in the second half of 2020.
- In February 2019, Fennec announced a $12.5 million debt financing with Bridge Bank, which will be funded upon New Drug Application (NDA) approval of PEDMARK™. The Company anticipates that its cash position of $22.8 million as of December 31, 2018 combined with the $12.5 million debt facility available upon approval of PEDMARK™ will be sufficient to fund the Company's planned commercial launch of PEDMARK™.

**Fourth Quarter and Year End 2018 Financial Results**

- **Cash Position** - Cash and cash equivalents were $22.8 million as of December 31, 2018.
- **Research & Development (R&D) Expenses** - R&D expenses were $1.7 million and $5.0 million, respectively, for the fourth quarter and year ended December 31, 2018, compared to $0.8 million and $1.9 million, respectively, for the same periods in 2017. The increase in R&D expenses were primarily due to the manufacturing and regulatory expenses associated with the preparation for regulatory approval and planned commercialization of PEDMARK™.
- **General and administrative (G&A) Expenses** - G&A expenses were $1.4 million and $5.4 million, respectively, for the fourth quarter and year ended December 31, 2018, compared to $1.6 million and $5.0 million, respectively for the same periods in 2017. Overall, there was a small decrease in non-cash equity compensation offset by small increases in administrative expenses.
- **Net Loss** - Net losses for the fourth quarter and year ended December 31, 2018 of $3.0 million ($0.15 per share) and $9.9 million ($0.52 per share), respectively, compared to $2.3 million ($0.15 per share) and $7.0 million ($0.47 per share), respectively, for the same period in 2017.

**Financial Update**

The selected financial data presented below is derived from our unaudited condensed consolidated financial statements which were prepared in accordance with U.S. generally accepted accounting principles. The complete audited condensed consolidated financial statements for the period ended December 31, 2018 and management's discussion and analysis of financial condition and results of operations will be available via www.sec.gov and www.sedar.com. All values are presented in thousands unless otherwise noted.

**Audited Condensed Consolidated**
**Statement of Operations:**
*(U.S. Dollars in thousands except per share amounts)*

| | Three Months Ended | | Twelve Months Ended | |
|---|---|---|---|---|
| | **December 31, 2018** | **December 31, 2017** | **December 31, 2018** | **December 31, 2017** |
| **Revenue** | $ - | $ - | $ - | $ - |
| **Operating expenses:** | | | | |
| Research and development | 1,723 | 886 | 5,008 | 1,936 |
| General and administrative | 1,382 | 1,629 | 5,401 | 5,015 |
| **Loss from operations** | (3,105) | (2,515) | (10,409) | (6,951) |
| **Other (expense)/income** | | | | |
| Unrealized gain/(loss) on derivatives | - | 206 | 167 | (134) |
| Other loss | 6 | (4) | 6 | (8) |
| Net interest income | 115 | 23 | 348 | 47 |
| Total other (expense)/income, net | 121 | 225 | 521 | (95) |
| **Net income/(loss)** | $ (2,984) | $ (2,290) | $ (9,888) | $ (7,046) |
| **Basic net income/(loss) per common share** | $ (0.15) | $ (0.15) | $ (0.52) | $ (0.47) |
| **Diluted net income/(loss) per common share** | $ (0.15) | $ (0.15) | $ (0.52) | $ (0.47) |

**Fennec Pharmaceuticals Inc.**
**Balance Sheets**
*(U.S. Dollars in thousands)*

| | **December 31, 2018** | **December 31, 2017** |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | $ 22,781 | $ 28,260 |
| Other current assets | 169 | 141 |
| **Total Assets** | $ 22,950 | $ 28,401 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities | $ 1,637 | $ 1,477 |
| Derivative liabilities | - | 167 |
| Total stockholders' equity | 21,313 | 26,757 |
| **Total liabilities and stockholders' equity** | $ 22,950 | $ 28,401 |

**Working Capital**

| Selected Asset and Liability Data: | Fiscal Year Ended December 31, 2018 | Fiscal Year Ended December 31, 2017 |
|---|---|---|
| *(U.S. Dollars in thousands)* | | |
| Cash and cash equivalents | $ 22,781 | $ 28,260 |
| Other current assets | 169 | 141 |
| Current liabilities excluding derivative liability | (1,637) | (1,477) |
| Working capital | $ 21,313 | $ 26,924 |
| | | |
| **Selected Equity:** | | |
| Common stock & APIC | $ 151,326 | $ 146,882 |
| Accumulated deficit | (131,256) | (121,368) |
| Stockholders' equity | 21,313 | 26,757 |

**About PEDMARK™ (sodium thiosulfate/STS)**

Cisplatin and other platinum compounds are essential chemotherapeutic components for many pediatric malignancies. Unfortunately, platinum-based therapies cause ototoxicity in many patients, and are particularly harmful to the survivors of pediatric cancer.

Each year in the U.S. and Europe there is estimated that over 10,000 children with solid tumors are treated with platinum agents. The vast majority of these newly diagnosed tumors are localized and classified as low to intermediate risk in nature. These localized cancers may have overall survival rates of greater than 80%, further emphasizing the importance of quality of life after treatment. The incidence of hearing loss in these children depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids. There is currently no established preventive agent for this hearing loss and only expensive, technically difficult and sub-optimal cochlear (inner ear) implants have been shown to provide some benefit. Infants and young children at critical stages of development lack speech language development and literacy, and older children and adolescents lack social-emotional development and educational achievement.

STS has been studied by cooperative groups in two Phase 3 clinical studies of survival and reduction of ototoxicity: COG ACCL0431 and SIOPEL 6. Both studies are closed to recruitment. COG ACCL0431 enrolled one of five childhood cancers typically treated with intensive cisplatin therapy for localized and disseminated disease, including newly diagnosed hepatoblastoma, germ cell tumor, osteosarcoma, neuroblastoma, and medulloblastoma. SIOPEL 6 enrolled only hepatoblastoma patients with localized tumors. COG ACCL0431 final results were published in the Lancet Oncology. SIOPEL 6 final results were published in the New England Journal of Medicine.

**About Fennec Pharmaceuticals**

Fennec Pharmaceuticals Inc., is a specialty pharmaceutical company focused on the development of PEDMARK™ (a unique formulation of sodium thiosulfate (STS)) for the prevention of platinum-induced ototoxicity in pediatric patients. STS has received Orphan Drug Designation in the US in this setting. Further, PEDMARK™ received Breakthrough Therapy and Fast Track Designation by the FDA in March 2018. Fennec has a license agreement with Oregon Health and Science University (OHSU) for exclusive worldwide license rights to intellectual property directed to STS and its use for chemoprotection, including the prevention of ototoxicity induced by platinum chemotherapy, in humans. For more information, please visit www.fennecpharma.com.

**Forward looking statements**

Except for historical information described in this press release, all other statements are forward-looking. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including such risks that regulatory and guideline developments may change, scientific data may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, the Company may not meet its future capital requirements in different countries and municipalities, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2018. Fennec Pharmaceuticals, Inc. disclaims any obligation to update these forward-looking statements except as required by law.

The scientific information discussed in this news release related to PEDMARK™ is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, Health Canada or other regulatory and no conclusions can or should be drawn regarding the safety or effectiveness of such product candidate.

For a more detailed discussion of related risk factors, please refer to our public filings available at www.sec.gov and www.sedar.com.

For further information, please contact:

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